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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/562,422	12/27/2005	Tina Rademacher	RO4126US (#90568)	3869

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EXAMINER	
WESTERBERG, NISSA M	

ART UNIT	PAPER NUMBER
1618	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/562,422	RADEMACHER ET AL.	
	Examiner	Art Unit	
	Nissa M. Westerberg	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 December 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1, 3 - 36* is/are pending in the application.

4a) Of the above claim(s) *15 - 19, 30 - 32, 36* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3 - 14, 20 - 29, 33 - 35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/27/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' arguments, filed December 10, 2008, have been fully considered but they are not deemed to be fully persuasive. The following rejections and/or objections constitute the complete set presently being applied to the instant application.

Election/Restrictions

1. The requirement for Restriction/Election is still deemed proper and is therefore made FINAL.

2. Claim 15 was a use claim which Applicant has amended to be a method of applying the film-shaped administration form. This interpretation of claim 15 was not elected in the response filed July 7, 2008. Therefore, claim 15 and new claim 36, which depends from claim 15, are withdrawn from further consideration.

Information Disclosure Statement

3. The Examiner thanks Applicant for full copies of the foreign patent and non-patent literature documents cited on PTO-1449. These documents have been considered, the citation for the Eaimtrakern et al. reference completed and a signed copy of this form included with this Office Action.

Claim Rejections - 35 USC § 112 – 2nd Paragraph

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 35 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. "Selected from the group consisting of" is used to introduce a Markush group of items, which contains more than one item. While this language is used in claim 35, what follows is only a list of one item so it is unclear if there should be more than one item in the Markush group which were omitted or if there really is only one item and that the Markush group language was not required.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 2 – 5, 7 – 11, 13 – 15, 21, 22, 24 – 26 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Kigasawa et al. (US 4,572,832). This rejection is

MAINTAINED for the reasons of record set forth in the Office Action mailed September 9, 2008 and those set forth below.

Applicant traverses this rejection on the grounds that there is only one passage in Kigasawa et al. where the pH is mentioned and so Kigasawa et al. does not teach film-shaped administration forms having a base mass adjusted to a physiological pH value as presently claimed. Only in Example 8(b) is a phosphate buffer of pH 6.5 used and this example does not include a drying step, which results in a gelled compositions and not the dried film required by the instant claims. Additionally, the present claims require that the pH is adjusted during production and because of the information provided by Kigasawa et al., the pH of the final mixture is unknown and it cannot be interpreted as disclosing a base mass which is adjusted to a physiological pH value as set forth in the present claims.

These arguments are not found to be persuasive. These claims are product-by-process claims so the determination of patentable is based on the product that is produced, not the method that is used to produce the product. Therefore what stage the pH is adjusted at is not material to the determining the patentability of the instant claims. Rather, the pH of the product is evaluated. The present claims do not require a specific pH value but rather one that is "approximated or adapted to the physiological pH values of the mucosas to which the administration form is to be applied". As indicated at ¶ 20 of the specification, the pH of various mucosa can be slightly basic (8 – 9) in herbivore oral mucosa or human nasal mucosa, or acidic (5.5 – 6.5 for human oral mucosa and around 4 for human vaginal mucosa). The compositions of Kigasawa et al. are

administered via a mucus membrane and therefore regardless of the exact pH of the final composition, the pH is "approximated or adapted to the physiological pH values of the mucosas to which the administration form is to be applied".

Both examples 8(a) and 8(b) contain a drying step and the final material has been dried in that the moisture content of the product has been reduced. In Examples 8(a), a specific air drying step is recited while in example 8(b), the mixture is compressed and extended with warming at about 50°C (col 12, ln 53 – 55), which will result in moisture loss and drying of the administration form. Applicant has not defined a "dried film" as being in a completely dry state, as not being a gel, or having a particular moisture level. Therefore, both of these administration forms met the limitation as to a dried film. Therefore all of the limitations are present in Kigasawa et al. and this rejection is MAINTAINED.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 1, 3 – 11, 13 – 15, 20 – 29 and 33 – 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kigasawa et al. (US 4,572,832). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed September 8, 2008 and those set below. This rejection is no longer applied to canceled claim 2 and is now applied to new claims 33 – 35.

Applicant traverses this rejection on the same grounds discussed above in regards to Kigasawa et al. The reasoning put forth by the Examiner as to why the claims

were rendered obvious by Kigasawa et al. are reiterated but no additional arguments in regards to the reasoning put forth by the Examiner are presented. Therefore, the rejection is MAINTAINED for the reasons discussed in more detail above.

In regard to the new limitations in claims 33 and 34, Kigasawa et al. teaches that pharmaceutically active ingredients in the salt from are suitable for incorporation into the soft buccal form. The salts triperizone hydrochloride, dantrolene sodium, cyclobenzaprine hydrochloride (col 2, ln 3 – 5) and ipratropium bromide (col 2, ln 33) are exemplified. Menthol, which reads on aroma substance, can be included in the soft buccal dosage from (col 1, ln 64 – 65). Therefore, a dosage with only menthol in the base mass will meet the limitation presented in claim 35 in which the active substance present in the film-shaped administration form is an aroma substance.

12. Claims 1, 3 – 14, 20 – 29 and 33 – 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kigasawa et al. as applied to claims 1, 3 – 11, 13 – 15, 20 – 29 and 33 – 35 above, and further in view of Rault et al. (US 5,900,247). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed September 8, 2008 and those set forth below.

Applicant traverses this rejection on the grounds that Rault et al. fails to cure the deficiencies of Kigasawa et al.

As discussed in greater detail, Kigasawa et al. is not deficient and therefore Rault et al. is not required to cure the deficiencies discussed above and this rejection is maintained.

Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nissa M. Westerberg whose telephone number is (571)270-3532. The examiner can normally be reached on M - F, 8:00 a.m. - 4 p.m. ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

NMW